

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION	: : : : : : :	Civil No. 19-2875 (RBK/JS) HON. ROBERT B. KUGLER HON. JOEL SCHNEIDER
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PLAINTIFFS' LIST OF "MACRO" DISCOVERY ISSUES

Plaintiffs hereby submit this list of proposed "macro" discovery issues to brief and decide before the December 11, 2019 conference:

- The corporate organization and interrelationship between Zhejiang Huahai Pharmaceutical Co. Ltd. ("ZHP") with Princeton, Solco, and Huahai U.S. , and potentially other defendant groups.
- Identification of the full scope of the valsartan sold in the United States, broken down by defendant (including all defendants, e.g., distributors, pharmacies) so that the Court and the parties may accurately determine the total sales numbers and prices for the overall market and for each defendant.
- Identification of contamination status of the all valsartan sold in the United States, traced back to and identified by batches and lots (or other logical quantifiers) manufactured, distributed or sold by each defendant.
- Defendants' document retention / destruction policies and litigation holds.

- Camber's non-service of objections and responses to Plaintiffs' first set of requests for the production of documents ("RFPs").
- Defendants' preliminary statements and general objections to Plaintiffs' first set of requests for the production of documents, and lack of substantiation/basis for Defendants' specific but largely boilerplate objections to each request in Plaintiffs' first set of requests.
- Defendants' limitation of responses to only certain entities and/or manufacturing facilities (e.g., Teva appears to carve out the Malta facility).
- Non-privileged facts and information in the possession of Defendants' outside counsel, including in its apparent role as liaison to the FDA.
- Identification of other products using the same manufacturing processes, solvents, and/or testing as those for valsartan API.
- Research and Development / manufacturing preparations for valsartan API pre-dating sale of API or finished dose into the United States.
- Plaintiffs' potential need for inspection of Defendants' facilities pursuant to Rule 34.
- All testing considered, used, or rejected for valsartan API and finished dose.
- Documents relating to valsartan API or finished dose that was never sold (e.g., proposed yet never submitted ANDAs or submitted ANDAs that were not approved).
- "Standardized" regulatorily-required documents such as certificates of analysis, cGMP standard operating procedures, etc.
- Inter-defendant communications and representation by counsel.
- Communications with Plaintiffs including named plaintiffs and putative class members.
- FDA inspection documents (including Form 483s, EIRs, and Warning Letters) for both API and finished dose manufacturing facilities involved in the manufacturing of

valsartan, which detail and describe generalized manufacturing issues and/or non-compliance with cGMPs.

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CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of October 2019, a true and correct copy of the foregoing was filed and served upon all counsel of record via the CM/ECF system of the United States District Court for the District of New Jersey.

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